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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/822,963      03/21/97      LIU

D      ENZ-56

EXAMINER

HM12/1011

RONALD C FEDUS  
ENZO THERAPEUTICS INC  
C O ENZO BIOCHEM INC  
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NEW YORK NY 10022

GUZD

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

10/11/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/822,963

Applicant(s)

Llu et al.

Examiner

David Guzo

Group Art Unit

1636

☒ Responsive to communication(s) filed on Sep 25, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 68-90 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 68-90 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Applicants, in the request for filing a CPA, did not request that the unentered amendment filed after final under 37 CFR 1.116 be entered and said amendment remains unentered.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 68-81, 83 and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Greatbatch et al.

Both applicants and Greatbatch et al. (U.S. Patent 5,324,643, issued 1/28/94, see whole document, particularly Columns 8, 12, 16 and 17) recite vectors (which can be viral or retroviral) which are capable of expressing exogenous nucleic acid sequences in target cells wherein said vector comprises at least one non-deletion modification (i.e. substitution of a polIII promoter which can be from a tRNA gene) with a non-retroviral sequence leading to an alteration of viral vector function and non-native or native terminator sequences. Therefore, Greatbatch et al. teaches the claimed invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 68-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 (and dependent claims) are vague in the recitation of the phrase "...non-deletion modification with a non-retroviral sequence leading to an alteration or enhancement of viral vector function." since it is unclear what relationship exists between the "non-deletion modification" and the "non-retroviral sequence".

Claim 74 is vague in that there is no antecedent basis for the term "the sequence segments" in claim 73. Also, claim 74 is vague in that the claim recites a sequence segment which is "not related" to promoter/enhancer sequences of a retrovirus. It is unclear what is meant by "not related", i.e. does this term mean other retroviral sequences which are not promoter or enhancer sequences or non-retroviral sequences, etc. Also, claim 74 does not further limit the subject matter of claim 73 in that the claim recites a substitution which can be a retroviral sequence as long as it is "not related" to a retrovirus promoter/enhancer sequence.

Claim 78 is vague in that there is no antecedent basis for the term "said viral vector terminator" in claim 68.

Claim 81 (and dependent claims) is vague in that applicants recite promoter/enhancer regions selected from genes. Promoter/enhancer regions are not genes, but are portions of the regulatory regions of genes.

Claim 85 (and dependent claims) are vague in that claim 85 depends from canceled claim 1.

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Claims 86 and 87 are vague in the recitation of the phrase "wherein said providing step or introducing step" since this phrase appears to be out of context with the rest of the claim and is not connected to the other claim language.

Claims 89 and 90 are vague in that the claims recite a nucleic acid construct that has been "modified" by means of an episome or by "transient expression". It is unclear how an episome or transient expression can modify a nucleic acid construct.

Note: With regard to applicants request, in the amendment filed 3/15/99, that the previously filed defective petition to correct inventorship under 37 CFR 1.48(b) be re-processed with a newly supplied consent of the assignee, it is noted that defective petitions cannot be corrected piecemeal. A new complete submission under 37 CFR 1.48(a) must be filed. Also, in the response filed 3/15/99, applicants indicate that the previous defective petition "...should have been filed under 37 C.F.R. 1.48(b) (emphasis added) and not 1.48(b)." This is erroneous since the petition should have been filed under 37 CFR 1.48(a) and cannot be considered under 37 CFR 1.48(b).

No Claims are allowed.

All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS**

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**ACTION IS MADE FINAL** even though it is a first action after the filing under 37

CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 or (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo  
October 5, 2000

DAVID GUZO  
PRIMARY EXAMINER  
*David Guzo*